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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,599	11/11/2003	George Jackowski	2132.135	5792

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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,599	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 7-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 7-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/9/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 6/9/2006 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claim 4-6 are cancelled.
2. Claims 1-3, 7-9 are under examination.

Deposit

1. With respect to claim 3, it is apparent that the 5F4 and 6G4 antibodies are required to practice the claimed invention.

As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

NOTE THE CURRENT ATCC DEPOSITORY ADDRESS
American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

Applicant is reminded that the following and should amend the specification accordingly.

The current address of the ATCC is as follows:

American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-3, 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, it is not clear what is the role of monoclonal antibodies from step (b) and step (c). The recited claim only detects a "statistically significant increase in the presence of an antibody-antigen binding complex formed by said monoclonal antibody of step (a)" for diagnostic purpose. There is no active step(s) further limiting or correlating monoclonal antibodies from step (b) and step (c). Applicant needs to clarify.

With respect to claim 1, step (e), it is not clear this "statistically significant increase" is compared to a normal non-heart failure population.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Rasamoelisolo et al. (Vox Sanguinis et al. (1997) Vol. 72, page 185-191, ***applicant submitted on 6/9/2006 IDS***).

Rasamoelisolo et al. teach using three sets of monoclonal antibodies specific for detection of glycophorin antigen. The three monoclonal antibodies includes, 3F4 capable of recognizing glycophorin A/B antigen on amino acid comprising residues 5-25; 6G4 capable of recognizing glycophorin A antigen on amino acid comprising residues 39-45; and 5F4 capable of recognizing glycophorin A antigen on amino acid comprising residues 107-119 (See Abstract; Figure 4). The samples are from blood products, such as RBC (See Materials and Methods).

With respect to the "wherein" clause in step (e), the clause does not recite any additional active method steps, but simply states a characterization or conclusion of the results of those steps. It is construed as a mental step and not considered to further limit the method defined by the claim and has not been given weight in construing the claims. See Texas Instruments, Inc. v. International Trade Comm., 988 F.2d 1 165,1171, 26 USPQZd 1018, 1023 (Fed Cir. 1993) (A "whereby" clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim."). See also Minton v. National Assoc. of Securities Dealers. lnc.. 336 F.3d 1373, 1381, 67 USPQZd1614, 1620 (Fed. Cir. 2003) ("A werebyclause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited").

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasamoelisolo et al. in view of Mak et al. (US 6190691).

Rasamoelisolo et al. reference has been discussed but does not explicitly teach using a second antibody attached with a label to detect the complex of the glycophorin-antibody.

Mak et al. teach modified ELISA using a labeled second antibody recognizing a first antigen-antibody complex to increase detection sensitivity and specificity (Col. 16, line 32-50).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Rasamoelisolo et al. with a labeled second polyclonal antibody specific for the antigen-antibody complex as taught by Mak et al. in order to increase sensitivity and specificity because such technique is well-known and widely practiced in the art.

With respect to claim 8-9, Mak et al. teach labeling the second antibody with peroxidase as the signal generating substance (Col. 16, line 45-50).

Response to Applicant's Arguments

Deposit

Applicant submitted ATCC deposit information for 3F4 monoclonal antibody and statement for "all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications" have been received and entered. Accordingly, applicant has complied with the deposit rule set forth in this Office. However, there is no information with respect to monoclonal antibodies **5F4 and 6G4** (emphasis added). Applicant submitted the French BioAlantic Inc. and a paper describing the production of these two monoclonal antiboes (See Rasamoelisolo et al., Vox Sanguinis (1997) Vol. 72, page 185-191). Applicant argues that (1) these two monoclonal antibodies are identical and described in the Rasamoelisolo et al. paper; and (2) the company of BioAtlantic is available for purchasing the said monoclonal antibodies. Thus applicant has fulfilled deposit rule, and the restriction should be withdrawn. Applicant arguments have been considered, but are not persuasive.

information is not clear whether these antibodies are commercially available. For instance, the two pages documents (submitted on 5/30/2006) merely describing at page 1, BioAtlantic Inc. offers to sell several antibodies for immunoglobulins, blood cells, and cytometry analysis. At page 2, it merely describes a location of the BioAtlantic Inc. There is no specific price, or name products for 5F4 or 6G4 monoclonal antibodies. Second, merely describing or illustrating the characteristics of the 5F4 and 6G4 antibodies in a scientific publication does not equate for commercial availability. There is no information indicating that the authors in the Rasamoelisolo et al. are selling the said antibodies. Therefore, applicant still requires to deposit 5F4 and 6G4 monoclonal antibodies in the ATCC pursuant to the deposit rule.

4. Applicant's arguments with respect to claims 1-3, 7-9 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 6/9/2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner
Art Unit 1641

August 7, 2006

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